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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,257	09/26/2003	Manssur Yalpani	CRB-T103X	8838

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MANSSUR YALPANI
6324 FERRIS SQUARE
SAN DIEGO, CA 92121

EXAMINER	
LUKTON, DAVID	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,257	YALPANI, MANSSUR	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 8-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' species elections are acknowledged, i.e., poly-*gamma*-Glu (per se) is administered, wherein the poly *gamma*-Glu has a molecular weight of 10^6 D and a polydispersity of about 1.

In accordance with applicants' previous election of Group 2 (claims 4-7), claims 1-3 and 8-17 are withdrawn from consideration.

✧

Revision of the abstract is required. The abstract should reflect the subject matter that is described in claims 4-7.

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-7 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have asserted that the various polymers referred to in claims 4 and 5 are effective to inhibit nitric oxide synthase. However, there is no evidence that this is the case. It is noted that there are various assertions on pages 34-36 about "neuronal rescue". Regardless of whether any of these assertions are

true are not, the fact is that there is no evidence that polyglutamic acid (or any other polymer) is effective to inhibit nitric oxide synthase.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims.

As it happens, one cannot "predict" biological activity merely by viewing the structure of a compound. And even if it should turn out that polyglutamic acid can inhibit apoptosis of H_2O_2-treated cerebral cortex cells, this finding will not support the assertion that poly-Glu inhibits the enzyme in question.

Accordingly, "undue experimentation" would be required to practice the claimed invention.

An issue separate from the foregoing stems from the fact that the claims encompass both of the following: (a) a method of inhibiting NOS in a mammal which would benefit from the inhibition, and (b) a method of inhibiting NOS in a mammal which would be harmed by the inhibition (or at least would derive no benefit). As it happens, the specification does not teach the skilled artisan how to use the polyglu in those cases where the subject would be harmed by the

administration. This particular ground of rejection can be overcome by reciting the following:

> *A method of inhibiting nitric oxide synthase III comprising administering to a mammal in need thereof one or more polyglutamate polymers ...etc.*

[However, if this language is adopted, the claims will remain rejected under §112, first paragraph, because the specification does not teach the skilled artisan how to inhibit NOS].

✦

Claims 4-7 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is drawn to a method of using a "polyglutamate polymer". Claim 5, by contrast, doesn't actually require that any glutamic acid residues be present. Claim 5 encompasses, for example, poly-aspartic acid, polyasparagine, and polyglutamine. Nor does claim 5 even require that the polymer at issue be a homopolymer. In accordance with art-recognized meanings of the terms "polyglutamic acid", "polyaspartic acid", "polyasparagine", and "polyglutamine", claim 5 is not properly subgeneric to claim 4. Furthermore, claim 5 permits "m" to be just 1. Accordingly, claim 5 would encompass any protein that contains at least one glutamic acid residue (or aspartic acid or glutamine).
A step in the direction of resolving this issue can be achieved by (a) casting claim 5 in independent form, and (b) by limiting claim 4 to polyglutamic acid (*per se*).

Claim 5 recites that "m" can be just 1. For the case of "m" being 1, what other monomer units are permitted? Letting "m1" represent integer variable "m" of formula I, and "m2" represent integer variable "m" of formula II, is it the case that the sum of m1, m2 and p must be sufficiently high that the molecular weight is at least 100 kD, or can the sum of m1, m2 and p be substantially less than that?

✦

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 4-6 are rejected under 35 U.S.C. §103 as being unpatentable over Troutt (USP 6,083,906).

Troutt discloses the use of the interleukin 17 receptor for inhibiting nitric oxide synthase. One of the proteins useful for this purpose is SEQ ID NO:3, which spans columns 27-32. As is evident, the sequence spanning residues 812-820 is the following:

-E-E-E-E-E-E-E-Q-D-

It is evident from a reading of (instant) claim 5 that applicants believe that glutamine falls within the scope of the term "glutamic acid", and that the same is true for aspartic acid. This is contrary to art-recognized terminology, but that is not the point. The point is that the sequence identified above is, in applicants' lexicon, a nonamer of glutamic acid. Thus, the protein identified in the reference is a "polyglutamate-containing polymer". The claims do not require that the term "polyglutamate polymer" refer to a homopolymer; the polymer in fact doesn't even have to contain a single glutamic acid residue. Given applicants very broad description of the term at issue, a polyglutamate-containing polymer meets the requirements of the claims.

✦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON, PH.D.
PRIMARY EXAMINER